

REMARKS

I. Claim Status

Claims 1-59 are currently pending in this application. Claims 5, 6, and 8-59 have been withdrawn from consideration. Claims 1 and 5 have been amended without prejudice or disclaimer.

II. Amendments to the claims

Claim 1 has been amended to recite “an isolated plurality of genes.” Support for this amendment may be found at least on page 10, lines 10-11 of the specification. Claim 1 has also been amended to read on the elected species “estrogen.” Support for this amendment may be found throughout the specification and in original claims 1 and 10.

Claim 5 has been amended to read on the elected species and as such is requested to be examined in the present case. Support for this amendment may be found throughout the specification and on page 25, lines 4-14.

No new matter has been added by the present amendments.

III. Rejections under 35 U.S.C. §101

Claims 1-4 and 7 have been rejected as allegedly being directed to non-statutory subject matter. Claims 1-4 and 7 have been amended to recite “an isolated plurality of genes” as suggested by the Examiner. Support for this amendment may be found at least on page 10, lines 10-11 of the specification. Applicants respectfully submit that the rejections under 35 U.S.C. § 101 have been fully obviated and should be withdrawn.

IV. Rejections under 35 U.S.C. §112, first paragraph

Claims 1-4 and 7 have been rejected as allegedly failing to comply with the written description requirement. The Examiner asserts that although the claims are directed to a plurality of any and all genes that are differentially expressed in kidney cells when exposed to estrogen and/or any other hormone, the specification allegedly only has limited support for a limited range of genes that appear to be differentially expressed and only in response to a limited number of agents. The Examiner cites to Chern *et al.*,

Nephron. 85:258-266 (2000) as being supportive of the difficulty in proving a full set of differentially expressed kidney genes.

Applicants respectfully traverse this rejection as being directed to the generic claim and not to the amended claims directed to the required elected species. Upon entry of the present amendments, the examined claims will encompass the elected species of: 1. estrogen; 2. the single combination of all of ABCC3, NNTT73, and CYP7B1 as the first group and; and 3. BHMT and SAHH as the second group. The elected species serve to define the scope of the claimed differentially expressed genes. The claims find adequate written description throughout the specification including in Example 4 and Table IV.

For all the foregoing reasons, Applicants respectfully submit that the rejections under 35 U.S.C. § 112, paragraph 1, have been fully obviated and should be withdrawn.

V. Rejections under 35 U.S.C. §102(b)

Claims 1-4 and 7 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Chern *et al.*, Nephron. 85:258-266 (2000). The Examiner asserts that since the claims are not limited to isolated genes, they allegedly are anticipated by whole kidney tissue of Chern (at page 259) and by the array of kidney genes, such as the 100,000 cDNA array and those genes listed in Table 1 (pages 260-261 and 265).

Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. See M.P.E.P. §2131 (8th Ed. Rev. 4, 2006). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Every element of the claimed invention must literally present, arranged as in the claim. *Perkin Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir. 1984).

Amended claim 1 recites “an isolated plurality of genes” as suggested by the Examiner; thus the claims cannot be anticipated by whole kidney tissue.

Additionally, Chern's array of kidney genes, such as the 100,000 cDNA array and those genes listed in Table 1, cannot anticipate claims 1-4 and 7, since Chern does not teach each and every element of the rejected claims. Chern does not disclose 1) differential expression of any kidney genes in response to **estrogen**; 2) or the differential expression of any of the specific genes recited in the elected dependent claims 5-7; 3) or the downregulation of any kidney genes. The claims require an isolated plurality of genes comprised of a first and second group of genes, wherein the first group is differentially expressed at a **higher level** in kidney cells exposed to **estrogen** and the second group is differentially expressed at a **lower level** in the kidney cells exposed to estrogen. This is not found in Chern.

Chern is silent regarding subsets of genes that exhibit increased expression in response to estrogen and those that exhibit lower expression to estrogen in kidney cells. Chern provides no teaching regarding genes that are differentially expressed in response to estrogen. Chern does not teach all of the elements of the rejected claims, and therefore does not anticipate the present application. Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) under Chern be withdrawn.

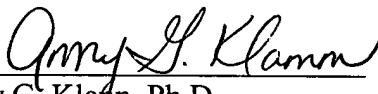
CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. Applicants reserve the right to pursue the canceled and/or non-elected subject matter in one or more continuation or divisional applications.

It is believed that no additional fees are required for these submissions. However, should the U.S. Patent and Trademark Office determine that any additional fee is required or that any refund is owed for this application, the Commissioner is hereby authorized and requested to charge any deficiency and/or credit any refund owed to our Deposit Account No. 04-0100.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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